

SCIENTIFIC AND REGULATORY PERSPECTIVES ON THE EMERGING ENVIRONMENTAL CONTAMINANTS ISSUE

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ABSTRACT

Emerging environmental contaminants include a wide variety of chemicals that have been largely outside of the scope of environmental regulation. Also referred to as PPCPs (pharmaceuticals and personal care products), these contaminants are derived from any product consumed by humans or animals for health or cosmetic reasons, and thus include prescription and non-prescription human drugs, veterinary medicines, and a wide variety of chemicals found in everyday products such as shampoo, soap and sunscreen. Emerging environmental contaminants (EECs) have stimulated a great deal of interest because their inputs to the environment are continuous and their effects are largely unknown. The purpose of this paper is to present an overview of the potential impacts of this issue to wastewater providers. The discussion will include the various types and occurrence of EECs and the relationship to endocrine disrupting effects, other possible environmental and human effects, potential treatment technologies and removal success, and current regulation and policy.

KEYWORDS

Emerging Environmental Contaminants, Pharmaceuticals, Endocrine Disruptors, Wastewater

INTRODUCTION

Environmental chemists are using increasingly sophisticated analytical techniques to investigate the presence of previously undetected contaminants in surface waters. These “emerging environmental contaminants” (EECs) include a diverse collection of thousands of chemical substances that have heretofore been largely outside the scope of monitoring and regulation in ambient waters. These chemicals are not found on the priority pollutant list. They are, however, constantly being discharged into the aquatic environment from point and non-point sources, at amounts believed to rival those of fertilizers and agricultural chemicals. Recently, these emerging environmental contaminants (EECs) have received significant coverage in scientific journals as well as the popular press, along with speculation about their possible effects upon human health and ecological processes.

The purpose of this paper is to present an overview of the potential impacts of the EEC issue to wastewater treatment providers with respect to the occurrence of EECs, their potential environmental and human health effects, removal technologies, and current regulation and policy. The impacts of the emerging environmental contaminant issue will be realized by many wastewater treatment facilities within the next decade. Utilities should be prepared to address citizens’ concerns about this issue by understanding the research that has been conducted and keeping abreast of new developments in the scientific and regulatory arenas.

The term EEC is very loosely defined, and alternative terms have been used as well. Pharmaceuticals and personal care products (PPCPs) is a term coined by Daughton and Ternes in 1999. Daughton has loosely defined PPCPs to include prescription and non-prescription drugs,

diagnostic agents, bioactive food supplements, personal care products, and any of the related transformation products. Sedlak (2002) defined pharmaceutically active compounds (PhACs) similarly to the Daughton definition of PPCPs, except that Sedlak excludes personal care products from the PhAC definition. Endocrine disruptors, or endocrine disrupting chemicals, are defined as any chemical that interferes with the function of the endocrine system. The endocrine system and the hormones it produces guides development, growth, reproduction and behavior. Endocrine disruptors are not specific to any one class of chemical. Only a small set of PPCPs are known or suspected of being endocrine disruptors.

There is no accepted or defined list of EECs. However, the broad subcategories include veterinary and human antibiotics, prescription drugs (e.g. codeine, anti-asthmatics, antacids), non-prescription drugs (e.g. acetaminophen, ibuprofen, caffeine), steroids and hormones (e.g. cholesterol, synthetic and natural estrogenic compounds), and organic wastewater contaminants (e.g. plastics, pesticides, detergents, fragrances, antioxidants, antimicrobial disinfectants). Some of these chemicals have been recognized as endocrine disruptors. Endocrine disruptors interfere with the function of the endocrine system, a system present in nearly all animals (including humans, fish, amphibians, birds, snails, crustaceans, and other species). Research suggests that the effect of certain EECs on the endocrine system are elicited at extremely low concentrations, hence the concern for endocrine-active substances in the environment. Table 1 summarizes the broad categories of EECs.

Several key issues impact the interpretation of EEC research and the potential for regulation:

- Aquatic and human health effects resulting from acute versus chronic exposure;
- Effect of simultaneous exposure to multiple chemicals and their potential synergistic effects;
- Detection versus quantification;
- Frequency of contaminant occurrence (seasonal, temperature, etc.);
- Contradictory and variable research; and,
- Current regulation and the potential for future regulation.

Current research is building upon previous work over the last decade, which has been conducted largely in Europe concerning the occurrence, fate, and transport of EECs and their metabolites, and their effects, particularly with respect to aquatic ecosystems. However, much of this research may be variable and very site specific to particular contaminants. Studies in the U.S. and Europe have intentionally sampled streams where contamination would be most likely. These types of studies are useful for developing analytical methods and identifying the nature of the EECs that may be present; however, these studies are not entirely predictive of the occurrence or behavior of a particular contaminant, or the response of the environment. Toxicology studies have also yielded inconsistent results. In part, these inconsistencies are attributable to the very subtle effects being investigated and the lack of validated test methods. Additionally, the reported removal rates of EECs in water and wastewater treatment processes vary considerably, depending upon the compound and the treatment system.

The detection of an EEC does not inherently or necessarily equate with a risk to human health or a risk to the natural environment. Both exposure and toxicity are necessary to constitute a risk. In addition, humans and aquatic organisms are exposed to a variety of chemical, physical and

biological stressors, making it difficult to interpret subtle effects and attribute them to a particular chemical detected at parts per trillion (ng/L) to parts per billion (µg/L) concentrations.

Table 1: A Summary of the Emerging Environmental Contaminant Categories

Category of EEC	Chemical Examples
Veterinary and Human Antibiotics	Tetracycline, ciprofloxacin
Prescription Drugs	Codeine, anti-asthmatics, antacids, antidepressants, blood lipid regulators, anti-epileptics, diclofenac ¹
Non-Prescription Drugs	Ibuprofen ¹ , acetaminophen ¹ , caffeine, aspirin ¹
Steroids and Hormones	Estrogenic compounds (estradiol ² , mestranol ³ , testosterone ⁴) Hormones (cholesterol)
Plastics	Bisphenol A ⁵
Detergents	Nonylphenol and octylphenol ^{6,7}
Antimicrobial disinfectants	Triclosan
Other	Fragrances, antioxidants

¹ Analgesic and anti-inflammatory drug

² Potent synthetic estrogen compound

³ Synthetic estrogen compound

⁴ Natural estrogen compound

⁵ Known endocrine disruptor

⁶ Suspected of being hormonally active

⁷ Industrial chemicals that are used as cleaning and sanitizing agents (detergents).

OCCURENCE

The occurrence of pharmaceutically active compounds in the aquatic environment has been investigated in several studies in Austria, Brazil, Canada, Croatia, England, Germany, Greece, Italy, Spain, Switzerland, the Netherlands, and the United States. A summary of this research (Heberer, 2002) concludes that more than 80 compounds from various prescription classes have been detected at concentrations up to µg/L in surface water, groundwater, and wastewater treatment plant effluent. To date, however, only a few instances of trace levels of these compounds have been found in drinking water. Figure 1 provides an illustration of possible sources and pathways of EECs into the environment.

In March of 2002, one of the most significant research papers to date on the occurrence of EECs in waters of the United States was published by the U.S. Geological Survey in *Environmental Science and Technology* (Kolpin et. al, 2002). This research was conducted over a period of five years. The primary objective of the study was to provide the first nationwide reconnaissance of the occurrence of over 95 wastewater contaminants in US waters. Contaminants were selected on the basis of common wastewater pathways into surface waters and previous research indicating prevalence of a particular contaminant in the environment, such as domestic and industrial discharges and agricultural run-off. The USGS study sampled 139 streams during 1999 and 2000. Each of the 139 streams was sampled in 1999, but only for subsets of those contaminants that were thought to be present based on land-use characteristics. Stream samples collected in 2000 were analyzed for all of the selected contaminants. New analytical methods and QA/QC procedures were developed for the detection of many of the contaminants (Kolpin et al., 2002).

The USGS discovered that one or more of the analytes were found in 80% of the 139 sampled streams. Eighty-two out of ninety-five contaminants were detected at least once during the study, and 75% of the streams sampled contained more than one contaminant. A total of 33 out the 95 contaminants are known or suspected to show weak hormonal activity with potential endocrine disrupting properties, and all 33 were detected in at least one stream sample during the study.

Measured concentrations of the contaminants were low, with few compounds exceeding drinking water guidelines, health advisories, or aquatic life criteria when these values existed (Kolpin et al., 2002).

The USGS divided the data into 15 groups based on general use and origin (steroids, non prescription drugs, insect repellent, detergent metabolites, disinfectants, plasticizers, fire retardants, antibiotics, insecticides, polycyclic aromatic hydrocarbons, hormones, antioxidants, fragrances, and solvents). For each of the 15 groups, the data was presented as a function of the frequency of detection and as a function of the percent of total measured concentration. It was found that 7 of the 15 groups were found in over 60% of the stream samples (Kolpin et al., 2002). However, 3 of the 15 groups, detergent metabolites, plasticizers, and steroids contributed over 80% of the total measured concentration. USGS concluded that out of the three categories receiving the greatest amount of public attention (non-prescription and prescription drugs, antibiotics), non-prescription drugs were found to have the greatest frequency of detection.

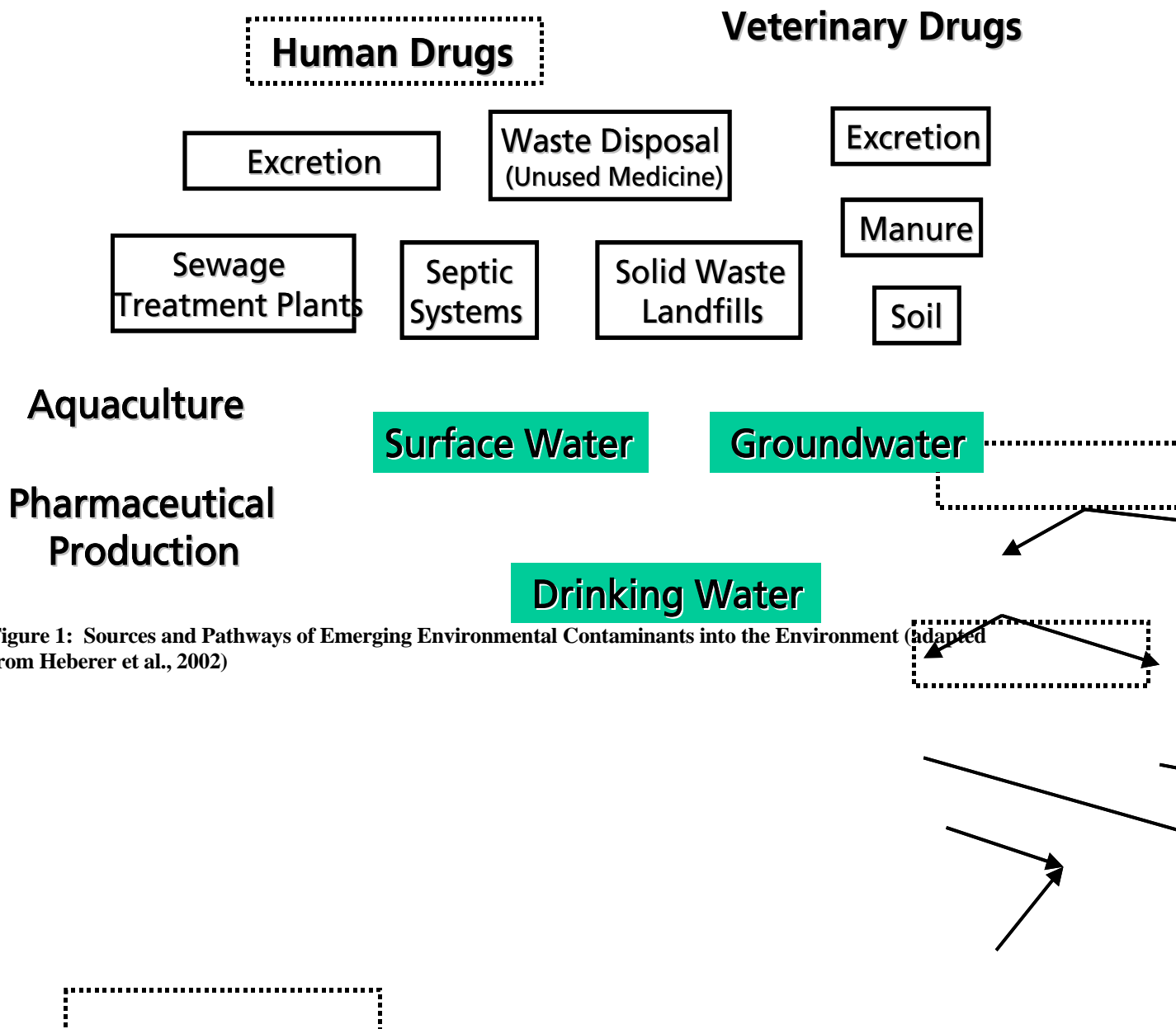


Figure 1: Sources and Pathways of Emerging Environmental Contaminants into the Environment (adapted from Heberer et al., 2002)

ENVIRONMENTAL AND HUMAN EFFECTS

The occurrence of a contaminant in surface water does not by itself signify that a risk to human health or the environment exists. Actual exposure to the contaminant must occur. Potential exposure pathways to surface water contaminants include direct contact, ingestion of the water, or ingestion of food organisms containing the contaminant. This latter pathway, via ingestion of food organisms, is unlikely for most of the EECs, since few appear to be bioaccumulative based upon their physicochemical properties.

If exposure can indeed occur, the next question to address is whether or not the magnitude, frequency and duration of the exposure are sufficient to cause an effect. In other words, are the concentrations high enough to cause effects, and do they occur often enough over a long enough period of time to produce effects? Relative to the latter two aspects, one of the concerns raised about EECs is their potential for continuous input into surface waters. The scenario is one whereby the general population uses pharmaceuticals and these substances (or their metabolites, which may be more or less biologically active) are then excreted, passing through wastewater treatment processes and occurring at a constant low level in the receiving water. Similarly, for veterinary products, the compound and/or its metabolites are excreted and the resulting manure or slurry is released directly to the environment or collected and stored before being applied to land, where the chemicals are then subject to runoff or leaching. Topically-applied products may enter the environment directly without passing through the animal. Aquaculture products may be directly used or released into the aquatic environment.

Human Health

A low concentration (e.g., ng/L to $\mu\text{g/L}$) of a particular drug in surface water is probably unlikely to represent a significant risk to humans, as the concentration is many orders of magnitude below the therapeutic dose. For most drugs, the therapeutic dose has been established based upon extensive testing and includes safety factors to protect sensitive sub-populations. Using conservative assumptions, it has been estimated that lifetime consumption of a drug at the low concentrations that have been observed in studies to date, through ingestion of drinking water at 2 liters per day, would lead to an exposure equivalent of only one or two therapeutic daily doses (Seiler, 2002). However, the intended human exposure to pharmaceutical and personal care products is structured. As patients receiving prescription medication or consumers buying over-the-counter drugs, people can be informed of conditions that preclude the use of certain drugs or be advised of potential drug interactions. They understand the frequency and duration of their exposure to the drug. Conversely, in the scenario involving surface water contamination with EECs, there is unintended exposure to a mix of various, unknown contaminants, over a long period of time (even lifetime), potentially including sensitive periods (e.g., reproduction and development). In addition, sensitive sub-populations (e.g., individuals with compromised immune systems or allergies) may be exposed. While human pharmaceuticals and personal care products tend to undergo centralized wastewater treatment, veterinary products are also released into the environment, typically with much less or no treatment, and these add to the mixture. Thus, although the concentrations of EECs that may occur in surface water are extremely low, and the potential for risk to human health is probably minimal, additional investigation is certainly warranted.

Ecological Effects

Of more concern is the potential risk to ecological receptors. Much less is known about the effects of EECs on aquatic organisms, but existing data indicates that aquatic life can be quite sensitive, at least to some contaminants. It must be emphasized that the amount of information required to secure regulatory approval to bring a new drug to market is vast. However, most of this information focuses on effects (both intended and side-effects) in the targeted organism (humans, or in the case of veterinary pharmaceuticals, certain animals). Regarding data generated on potential ecological effects, the requirements vary considerably depending upon the regulatory program under which the chemical falls. This may range from no data at all, to a base set of acute toxicity data (essentially tests for lethality) on three aquatic species (a fish, an invertebrate and a green alga), to more extensive testing. While the acute toxicity tests are good screening tools, they are not sufficient to identify more subtle effects (e.g., reproduction, growth, development, hormonal homeostasis) that can ultimately have significant effects on the aquatic ecosystem. In both vertebrates and invertebrates, hormones affect a number of physiological processes. For example, in rainbow trout, reproduction is controlled by natural estrogens in females and androgens in males. Females produce high concentrations of a protein called vitellogenin, a precursor of egg yolk. The occurrence of vitellogenin in male fish is an indicator of exposure to estrogen, and this response has been observed in male rainbow trout exposed to the biodegradation products of alkylphenol polyethoxylates, a major group of nonionic surfactants (Jobling et al., 1996). Jobling et al. (1996) found that exposure of trout to octylphenol, nonylphenol and related compounds at concentrations of approximately 30 µg/L also resulted in effects on spermatogenesis and testicular growth. Antidepressants appear to cause neuroendocrine disruption in fingernail clams that affects reproductive processes (Fong, 1998). Ethinyl estradiol (EE2), the synthetic estrogen used in human oral contraceptives, has elicited effects in rainbow trout at 2 ng/L (Jobling et al., 1996), and in a life-cycle study with fathead minnows at 4 ng/L (Lange et al., 2001). Short-term exposure to EE2 did not affect the amphipod *Gammarus pulex*; however, long-term exposure did affect population parameters, such as sex ratio, at concentrations as low as 100 ng/L (Watts, 2002). Of 17 compounds tested for effects on development of the copepod *Acartia tonsa*, the most potent were EE2, 4-octylphenol, and tamoxifen with 5-day EC₅₀ values of 88 µg/L, 13 µg/L, and 49 µg/L, respectively. Two natural estrogens (17β-estradiol and estrone) and the chemical bisphenol A were an order of magnitude less potent (Andersen et al., 2001). Exposure of daphnids to 100 µg/L nonylphenol significantly decreased reproduction but had no effect upon survival of the parental organisms (Baldwin et al., 1997). Thus, there is accumulating evidence that the basic screening ecotoxicology tests are not identifying sub-lethal effects that could occur in aquatic animals.

Microorganisms, algae and aquatic vascular plants are also important components of aquatic ecosystems and can be affected by EECs. It is not surprising that microorganisms are quite sensitive to antibiotics. The EC₅₀ for the antibiotic ciprofloxacin was 5 µg/L for the cyanobacterium *Microcystis aeruginosa*, 0.6 mg/L for activated sludge, and 2.97 mg/L for the green microalga, *Selenastrum capricornutum* (Halling-Sorensen et al., 2000). Recent findings indicate that higher vascular plants, such as duckweed, are also adversely affected by exposure to ciprofloxacin (Richards et al., 2002).

Although there is not much information on the ecological effects of individual EECs, even less is known about their effects in the combinations that are likely to occur in the environment. The first study to investigate mixtures of pharmaceuticals in aquatic ecosystems found that a mixture of the

painkiller ibuprofen, the antidepressant fluoxetine and the antibiotic ciprofloxacin had significant effects on experimental microcosms (Richards et al., 2002). The microcosms, containing bacteria, zooplankton, phytoplankton, plants and fish, were dosed with low, medium and high concentrations of a mixture of the three drugs and observed over 35 days. The medium and high dose microcosms demonstrated an increased abundance of phytoplankton and zooplankton, but the diversity of the community decreased, and toxicity was observed in duckweed and sunfish. Although the concentrations of the drugs used in the study were orders of magnitude higher than those that have been reported occurring in the environment, the effects upon the microcosm community were significant.

WATER AND WASTEWATER TREATMENT IMPACTS

Over the past decade, investigators in Germany, England, Sweden, France, and Canada have studied the occurrence and fate of EECs via water and wastewater treatment. Scientists in the United States are just beginning to study the occurrence of EEC in surface waters, and very few US researchers have published data on the fate of EECs. This section of the paper summarizes some of the research concerning the occurrence and fate of EECs during treatment.

Pharmaceuticals

Most of the available literature on pharmaceuticals in the environment deals with detection in the aquatic environment and not the environmental fate subsequent to treatment and/or release. Available research data concerning pharmaceuticals in drinking water, surface water, and wastewater treatment is inconsistent with respect to removal efficiencies of various treatment technologies. More than 80 pharmaceutical compounds and their metabolites have been detected at very low levels ($\mu\text{g/L}$) in municipal wastewater treatment plant effluents and surface waters (Heberer, 2002). Pharmaceutical compounds have also been detected in groundwater, particularly groundwater with potential contamination from landfill leachate or manufacturing residues. Some pharmaceuticals are removed by bank filtration prior to drinking water treatment because some compounds naturally attenuate in the soil. Other research has suggested that ozonation and membrane filtration will remove pharmaceuticals from drinking water, surface water, or POTW effluents (Heberer, 2002). Table 2 provides a list of a few categories of pharmaceutical contaminants that have been extensively studied in Europe with respect to treatment fate or occurrence.

Minimal pharmaceutical removal data exists for primary and secondary treatment, and almost no data exist for advanced wastewater treatment plants. A study in 1981 evaluated the ability of 14 wastewater treatment plants to remove endogenous and synthetic estrogens from wastewater. It was found that 5 to 25% of synthetic estrogens were removed by facilities employing primary treatment and 20 to 40% of synthetic estrogen was removed in facilities with secondary treatment. Natural hormones were removed 35% to 55% by primary treatment and 50 to 70% by plants with secondary treatment (Davis et al., 1999). Research at the University of California at Berkeley evaluated estrogen removal with membranes. Estrogen removal efficiencies for microfiltration and filtration were nearly the same. Reverse osmosis achieved the highest rate of removal of estrogens, however some estrogens still persisted in the effluent (Davis et al., 1999).

Table 2: Summary of European Pharmaceutical Research with Respect to Wastewater, Drinking Water, or Groundwater Treatment (data compiled from Heberer, 2002)

Contaminant	Location	Treatment Technology	Research Results	Principle Investigator
Salicylic Acid	WWTP Effluent	Activated Sludge	88% removal	Heberer
Diclofenac (analgesic and anti-inflammatory drug)	WWTP Effluent	Activated Sludge	17% removal	Heberer
	WWTP Effluent	Activated Sludge	69% removal	Buser et al.
	Drinking Water	Bank Filtration	Trace amounts in effluent	Verstraeten
	Drinking Water	Ozone		Zweiner & Frimmel
	Drinking Water	Membranes	Trace amounts in effluent	Heberer; Sedlak
	WWTP Effluent	Membranes	Trace amounts in effluent	Heberer; Sedlak
Ibuprofen	WWTP Effluent	Activated Sludge	Significant removal, except for one metabolite	Stumpf et al.
	WWTP Effluent	Activated Sludge	Significant removal, includes all metabolites (96 – 99.9% removal)	Buser et.al
Antibiotics	Drinking Water	Bank Filtration	Significant removal	Heberer et al.
	Surface Waters	Raw Water	Trace amounts in effluent	
	WWTP Effluent	Activated Sludge	Trace amounts in effluent	Hirsch et al.
Antiepileptic Drugs	WWTP Effluent	Activated Sludge	< 10%	
	Drinking Water	Bank Filtration	No removal	Kuehn & Mueller; Brauch et al.; Heberer et al.
Beta-Blockers	WWTP Effluent	Activated Sludge	Trace amounts in effluent	Hirsch et al.
Blood Lipid Regulators	Drinking Water	Bank Filtration	No removal, but metabolites removed	Scheytt et al.
Chemotherapy Drugs	WWTP Effluent	Activated Sludge	No removal	Kummerere et al.
Contraceptives	WWTP Effluent		Trace amounts in effluent	Desbrow et al.; Belfroid et al.; Spendgler et al.; Ternes et al.; Alder et al.
	WWTP Effluent	Activated Sludge	85% Removal of Estradiol	Baronit et al.
	WWTP Effluent	Activated Sludge	No removal of Estradiol	Ternes et al.
	Groundwater		Positive Detection	Adler et al.
	Drinking Water		Positive Detection	Adler et al.

Other Organic Constituents

The Environmental Protection Agency released in March 2001 a manual on the removal of endocrine disruptors in drinking water treatment. This EPA literature review primarily focuses on endocrine disruptor compounds that fall under the organic wastewater contaminants category: pesticides, highly chlorinated compounds, alkylphenols, and plastic additives. The EPA research found that granular or powdered activated carbon is the best available technology for removing various pesticides and alkylphenols.

An example of an organic wastewater constituent that has been the focus of numerous studies in the United Kingdom is the alkylphenols and their metabolites. Nonylphenol and octylphenol are used to make alkylphenol ethoxylate (APE) surfactants. These surfactants are the primary active ingredients in industrial chemicals used as cleaning and sanitizing agents. Nonylphenol ethoxylates (NPE) account for 80% of total APE use. Nonylphenol is a weakly estrogenic compound, and studies have shown that NPE can occur at relatively high concentrations in

wastewater treatment plants (parts per million ranges). Studies have shown that NPE removal from wastewater ranges from 92 to 99% with minor seasonal variations. NPE concentrations in discharges after municipal wastewater treatment are between 50 and 200 ppb.

RISK ASSESSMENT, REGULATION AND POLICY

In a risk assessment, information about exposure is integrated with information about effects to provide an estimation of the magnitude and likelihood of adverse effects. Risk assessment schemes typically proceed from very simple, screening approaches to more refined, data-intensive approaches. In essence, the risk assessment compares the concentration of the contaminant in the environment to the concentration that is not expected to cause adverse effects. In most approaches, the exposure and the effects are thus each reduced to a single number, which are then compared to each other by expressing them as a quotient. While the assumptions, data, and models that are used change, conservative assumptions and safety factors are used in derivation of both the numerator and the denominator. The results of the risk assessment are then used to make risk management or policy decisions.

In the U.S., there are two primary avenues for regulation of chemicals in the environment: pre-market and post-market. In the “pre-market” scenario, chemicals are evaluated for potential risk to human and environmental receptors before they are approved for use, while other statutes address chemicals after they have been used and released into the ambient environment (a “post-market” scenario).

Several EECs are already subject to pre-market regulation. The U.S. EPA regulates chemicals that are classified as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and regulates other chemicals under the Toxic Substances Control Act (TSCA). These statutes require the manufacturer to provide information on the fate and effects of chemicals, thereby allowing EPA to perform a risk assessment that results in decisions about how a product may be used. Pharmaceuticals are specifically exempted from the provisions of FIFRA and TSCA. Regulation of drugs falls under the Federal Food, Drug and Cosmetic Act (FFDCA), administered by the U.S. Food and Drug Administration (FDA). The approval of a new drug by the FDA is considered a major federal action significantly affecting the environment and thus the provisions of the National Environmental Policy Act (NEPA) are triggered, requiring preparation of an Environmental Assessment (EA). The EA requires that the fate and effect of any new drug to the environment must be evaluated. However, there is a categorical exclusion under FDA policy leading to the approval of drugs without an EA. A new drug can be approved if the concentration of that drug that is expected to enter the aquatic environment is less than 1 µg/L.

The approach differs in Europe, where the European Agency for the Evaluation of Medicinal Products has proposed a tiered environmental risk assessment scheme that is more rigorous. In this scheme, the first tier consists of deriving a rough estimate of the predicted environmental concentration (PEC) of a human pharmaceutical, based upon predicted amounts used and specific removal rates in sewage treatment or surface waters. If this crude PEC is less than 0.01 µg/L and no environmental concerns are apparent, no further risk assessment is required (Straub, 2002). A tiered environmental risk assessment scheme has also been developed in the European Union for veterinary medicinal products that considers the PEC in soil, surface water and groundwater (Koschorreck et al., 2002). Recently, Canada has implemented new requirements for ecological assessments of all new products regulated under Canada’s Food and Drugs Act.

A significant shortcoming of existing approaches to assessing the environmental risks of EECs is that cumulative (additive/synergistic/antagonistic) impacts of contaminants affecting similar receptors are not considered. Consideration of cumulative impacts is further complicated where chemicals have multiple uses and sources that fall under different regulatory programs. For instance, the antimicrobial compound triclosan is widely used in consumer and personal care products (e.g., liquid soaps, toothpaste) and is regulated by both the FDA and the EPA. However, at present, each agency evaluates triclosan independently and thus the totality of sources, uses and exposures in US surface waters is not being assessed.

In summary, the specific provisions of these statutes as well as differing agency policies and practices have led to a varying degree of evaluation and regulation of EECs to date in the pre-market environment. Pre-market regulatory risk assessments do not account for the cumulative exposure and risks of chemicals regulated by different statutes and agencies. Drugs and other FDA-regulated chemicals may be categorically excluded from environmental risk assessment, but may still contribute to cumulative exposure and risk. After receiving initial regulatory approval, there is typically little or no quantitative re-assessment of exposure and risk (pesticides are the exception).

In the U.S., once chemicals are present in surface water or ground water (the post-market environment), they are regulated under the Safe Drinking Water Act (SDWA) and the Clean Water Act (CWA). The SDWA establishes the acceptable concentration of constituents in drinking water delivered to consumers. Regulation under the SDWA requires sufficient data to demonstrate that the contaminant is known or likely to occur at levels that may adversely affect human health and that regulating the contaminant will provide meaningful improvement to public health. Under the CWA states are required to establish water quality standards based upon ambient water quality criterion (AWQC), or the amount of a chemical that can be present and still allow the water body to support its designated uses. The US EPA has developed AWQC for a list of “priority pollutants”, but this list does not include most EECs. The list of priority pollutants arose out of a consent decree in the 1970’s and was based upon known use, occurrence, and the analytical chemistry methods available at the time. The CWA regulates chemicals in surface waters at the “back end” by controlling point sources and increasingly, non-point sources.

There are several regulatory issues that need to be addressed in the post-market environment. First, are there risks to human health or aquatic life that should be addressed through the Safe Drinking Water Act and the Clean Water Act? There is a strong need for new analytical methods, sensitive ecological effects test methods, and environmental fate data, all of which preclude effective regulation at the present time.

As with so many different types of environmental pollutant concerns, the regulatory and policy considerations associated with EECs are fraught with complexity. Formulating sound policies and regulations to better manage risks to chemical pollutants requires a solid scientific basis as well as satisfactory economic analysis of the alternatives. At this time, there exist information gaps in both the science and economics in terms of policy decision-making even though progress is apparent.

The Role of Science

There are a number of outstanding scientific questions relative to EECs to answer that would help in formulating policy choices, many of which are subject to research. One of the more important yet quite general concerns is the lack of global consistency when defining “Emerging Environmental Contaminants” and “Endocrine Disrupting” compounds. Due to the global nature of this issue it is without doubt difficult to find consensus in definition yet imperative if for no other reason than to make the volumes of data being archived more transferable and useful to multi-stakeholder groups. In addition, informed policy and regulation require better understanding of effects and complex interactions in the environment. For example when discussing the effects of estrogen, what is normal vs. abnormal? What are adverse vs. non-adverse environmental effects? Are biological effects a result of antagonism or synergism? The broad range of chemicals considered as EECs poses uncertainty regarding the effects of chemical mixtures, metabolites, and transformation products that occur in various environmental media (environmental fate and transport). As can be seen, the development of scientifically sound regulation and policy surrounding EECs is going to require more multi-disciplinary research, improvements in risk assessment protocols, and uniformity in global research initiatives.

Economic Considerations

Determining how to manage and mitigate EEC concerns using policy and regulatory tools requires robust consideration of economic impacts to a wide range of industries and environments. Based on U.S. Census data for industrial sources of the specific group of compounds that are potential endocrine disruptors alone, the cumulative annual payroll from four of the primary sources was estimated at \$64 billion dollars (paper products, agricultural chemicals, pharmaceuticals, plastics manufacturing). These sectors ship over \$430 billion of products annually. The global nature of EECs thus creates a policy environment for which trade implications and macroeconomic effects (regional and industrial scale) impacts require attention. On a microeconomic scale there are economic variations of material/product flows within industrial sectors to be considered as well. The viability of a regulation or policy that forces an industry to find substitute inputs in effect depends on the availability of substitutes (and what is known about them in terms of science). Mitigation costs are also variable with respect to the type of environmental impact and across industries. Certainly the development of sound policy requires analysis of costs-benefits associated with externalities, trade-offs, and transfers of risk. When it comes to considering the restriction of the use of a life-saving drug, these benefits are of extreme importance.

The wastewater treatment sector serves as a good example of the complex policy considerations surrounding the EEC issue. The AWWA and EPA estimated in 2000-2001, 2% of community water systems are large (serve 50,000 or more individuals) and provide 56% of households with community water, whereas small systems comprise 98% of the total and serve 44% of households with community water (Kleinman, 2000). In addition nearly 15% of the U.S. population accesses a private water supply. Considering arsenic contamination as an example, the EPA estimated compliance with the new arsenic regulations would add \$181 million to wastewater treatment costs or from \$0.86 to \$32/household served by large systems and \$38 to \$327/household served by smaller systems. This exemplifies how important it is to evaluate economic implications and alternatives in terms of multiple pollutants in wastewater and subsequent treatment requirements. It is possible treatment techniques and associated capital investments could be evaluated to address

foreseen contaminants of concern and multiple compounds rather than on a single pollutant basis, thus creating more efficiency in economic returns.

CONCLUSIONS

The science of EECs is very complex. The sheer number of the chemicals involved, their complex fate in treatment systems and in the aquatic environment, and their largely unknown effects on the human population and aquatic ecosystems pose significant obstacles to appropriately dealing with this issue. The coverage given in the popular press with regard to recent scientific studies on this topic has led to concern among the general public. According to Kramer (2000), EECs are a classic example of how the public deals with risk. The public fears and ranks unknown risks higher than normal everyday risk. Endocrine disruptors fall into the unknown risk category. According to Kramer, EECs have all the classic characteristics to cause great fear in the public and will most likely lead to greater public awareness. Public utilities are likely to feel the pressure of public concern, potentially translating into huge infrastructure costs, or at least, translating to significant risk communication campaigns.

Although more rigorous scientific assessments are beginning to be applied to EECs, there are still many missing pieces of information that are required to inform the policy decisions about environmental risk. The understanding of the fate and transformation of these compounds in the environment, a more refined estimate of the potential exposure scenarios, the applicability of short term toxicity tests to elucidating long term effects, and the lack of cumulative or aggregate risk assessment approaches are all examples of information concerns important to the policy process.

The global nature of this issue adds to the challenge in terms of economic implications and viable regulatory measures. The vast array of industries potentially impacted by regulatory decisions and associated costs complicate the policy process, as does the need to consider both macro- and micro-economic concerns.

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